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Tailoring the EPLC

A Clinical Center Approach

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Discover America's Research Hospital.
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Objectives

- DCRI – Who we are
- CC Project Request Process
- Overview of CC Tailoring Process
- Examples of Tailored Projects
- Challenges
- Lessons Learned



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Who is DCRI?

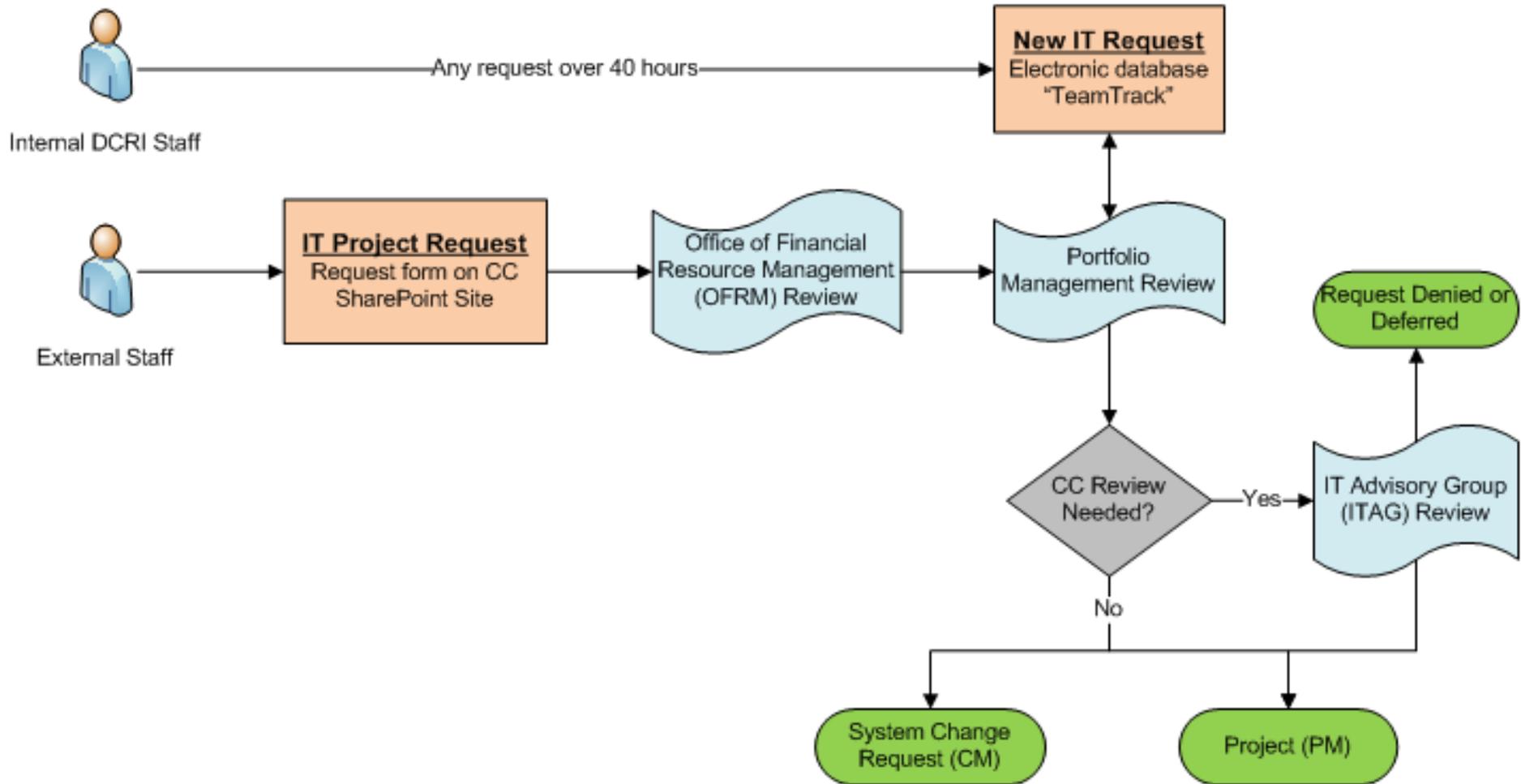
Department of Clinical Research Informatics (DCRI)

- **Mission Statement:** The Department of Clinical Research Informatics (DCRI) is committed to delivering secure, responsive, high-quality, customer-oriented information technology services and support that foster clinical care and research.
- 94 FTE (plus 10 contractors) in various teams, including:
 - Security and Privacy
 - Application Development and Clinical Build
 - Technical and Clinical Customer Support
 - Server Support and Data Center Operations
 - Project Management Office, Architecture, and Configuration Management



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CC IT Project Request Process





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IT Project Request Form

- Gathers information, similar to a project charter
 - Project objectives
 - Justification and Need
 - Relation to DHHS/NIH, CC, or department goals
 - Impact (Clinical, Protocol, Staff, Patient Care, etc.)
 - Resources required
 - Training needs
 - Knows risks, constraints, and assumptions
 - Security & Privacy
 - Procurement



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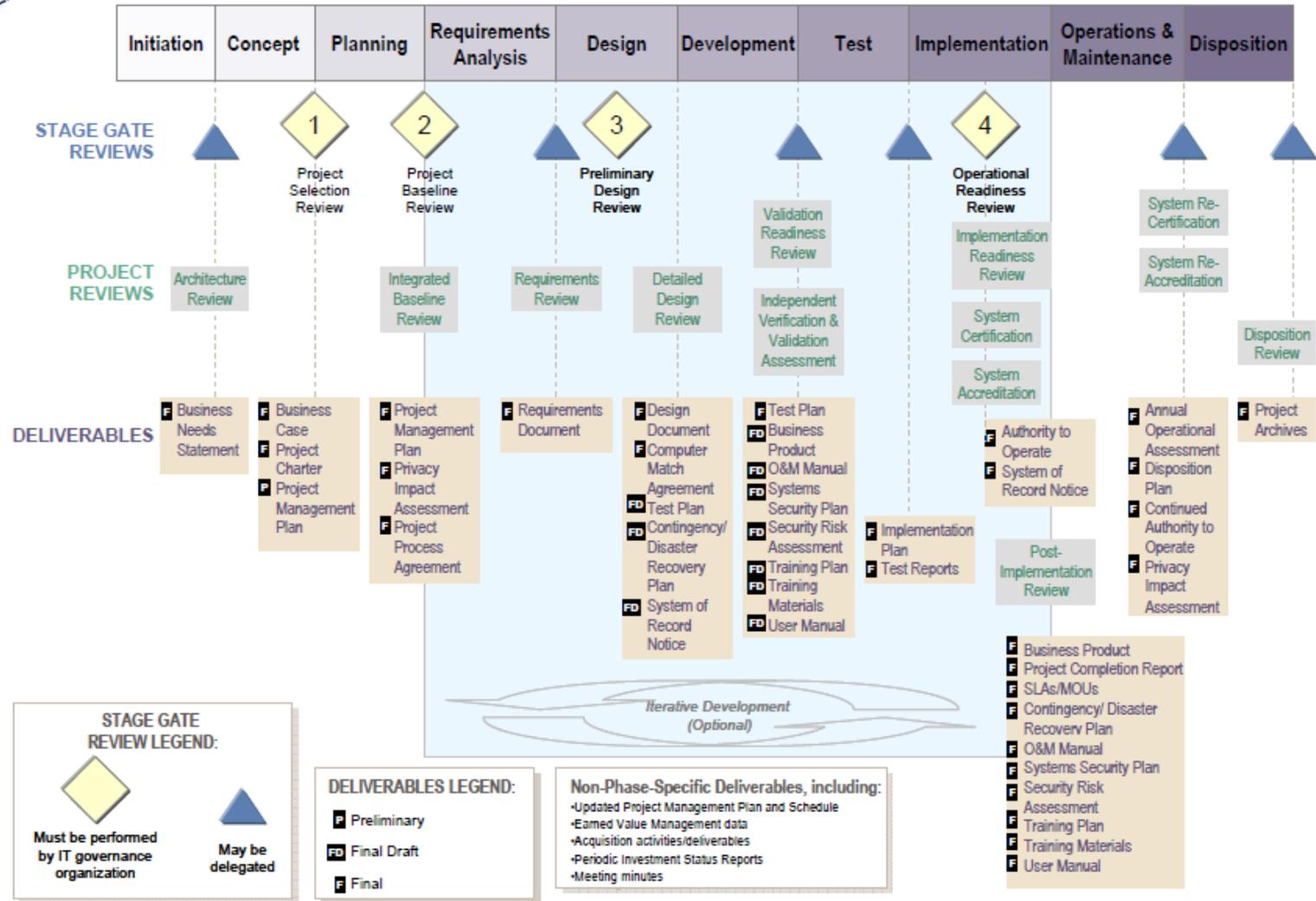
CC Project Definitions

- Every project falls under EPLC, but the phase may vary
- A new request is categorized into one of four options:
 - EPLC Project
 - Operations & Maintenance Project
 - Initiative
 - System Change Request (Standard Configuration Management)



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The EPLC Framework





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The Tailoring Process – Portfolio Level

EPLC Process	DCRI PMO Equivalent	Source	EPLC Project	O&M Project	Initiative
Initiating		Initiation			
Business Needs Statement	New Project Request	Template	X		
Architecture Review	Technical Review (completed in planning)	TIPs	X	X	X
Stage Gate Review	Stage Gate Review	Template	X		
Concept		Initiation			
Business Case		Document	X		
Project Charter		Document	X	X	
Project Selection Review	New Project Review	TIPs	X	X	X
Planning		Planning			
Project Process Agreement	Project Planning Checklist	Template	X	Optional	Optional
Project Management Plan	Project Scope	TIPs	X	X	X
	Roles & Contacts	SharePoint	X	X	X
	Communication Plan	SharePoint	X	X	X
	Risk ID & Analysis	TIPs	X	X	X
	Project Workplan	MS Project	X	X	SharePoint



The Tailoring Process – Project Level

- Each EPLC deliverable is reviewed by the PM to determine if it will be included in the project
- Justification needed for items not included
- EPLC tailoring document must be signed by project sponsors
- Stage Gate Reviews remain mandatory

Include?		EPLC Process	DCRI PMO Equivalent		
Yes	No	Deliverable	Deliverable	Source	Justification if Not Included in Project
		Design	Executing & Controlling		
✓		Design Document	Tech. Req or Mapping Document	Template	
	✓	Computer Match Agreement		N/A	Project started prior to December 1, 2008
✓		Detailed Design Review	(Reviewed by team when defined)		
✓		Preliminary Design Review	Technical Req Approval	Signature on Document	
		Development	Executing & Controlling		
✓		Test Plans	Test Plan & Test Scripts	Template	
✓		Validation Readiness Review		Document	
	✓	IV&V Assessment		N/A	IV&V not included on project
✓		Stage Gate Review	Stage Gate Review	Template	



Adding EPLC to Project Workplan

Task Name	Duration	Resource Names
Project XYZ	133 days	
Planning Phase	10 days	
Identify C&A team	3 days	Chief of Security & privacy team
C&A Kick-off meeting	1 day	Security POC,SO,PM,TPOC
Complete PIA and SORN (if applicable)	10 days	SO,PM,TPOC,Privacy POC
Complete FIPS 99	5 days	Security POC,SO,PM,TPOC
Complete ETA/ERA	1 day	SO,Security POC,PM,TPOC
C&A Technical Meeting	1 day	SO,Security POC,TPOC
Define System Boundaries	3 days	SO,Security POC,TPOC
Define Baseline Configuration	10 days	SO,TPOC,Security POC
Define Inheritance Control Matrix	3 days	SO,Security POC,TPOC
Design Phase	15 days	Security POC
Design Security Requirements (Complete Drafts)	15 days	
Contingency Disaster Recovery Plan	15 days	Security POC and TPOC
Development Phase	15 days	
Develop Draft System Security Plan (SSP)	15 days	SO,PM,TPOC
Code Freeze	0 days	
Implementation Phase	39 days	
Execute Security Test and Evaluation (ST&E)	30 days	Security POC,SO,TPOC
Finalize SSP	5 days	Security POC
Enter Test Results into NCAT	10 days	Security POC
Finalize Security Assessment Report	3 days	Security POC
Finalize Risk Assessment Report	5 days	Security POC
Discuss system weaknesses with SO/TPOC	5 days	Security POC,SO,TPOC
Create Plan of Action and Milestones (POA&M) items in N	3 days	Security POC
Program Manager Review	3 days	Security POC,PM
Develop ATO Letter & Risk Acceptance Waivers (if appli	2 days	Security POC
ATO Granted & Risk Acceptance Waivers signed	1 day	CIO,Security POC
Develop MOUs/ISAs	20 days	Security Office,PM,Vendor,SO
Operation & Maintenance Phase	10 days	
Annual Review of PIAs	5 days	Privacy POC,SO,TPOC
Annual Security Assessment	10 days	Security POC,SO,TPOC
Quarterly Review of POA&M weaknesses	5 days	Security POC,SO,TPOC

Deliverables that have similar tasks have a standard workplan template that can be added to a project



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Example Projects

- EPLC
 - Enterprise Scheduling Implementation
 - Radiology System Replacement
 - Barcode Medication Administration Implementation
- O&M
 - Hospital Information System Upgrade
 - New Lab Interfaces
 - Disaster Recovery & High Availability for CC Apps
 - Patient Portal
- Initiative
 - Nutrition System Upgrade



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EPLC Tailoring Challenges

- Project requests submitted after procurement/approval
- Complex environment creates unclear early requirements
- EPLC compliance from non-DCRI departments
- Needs of CC administration differ from IT & PMO

EPLC Tailoring Lessons Learned



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- Communicate process early and often
- Create a methodology for tailoring projects of various sizes
- Identify standard templates for deliverables
- Include sponsors in tailoring decision and approval
- Have a single point person to manage the EPLC process and related quarterly reports



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Q&A

Thank you! Questions?

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